UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENESSEE
WESTERN DIVISION

ELNORA JONES, Plaintiff, vs. ABBOTT LABORATORIES, Defendant.	CASE NO.:

COMPLAINT

COMES NOW, ELNORA JONES, by and through the undersigned counsel, and brings this action for damages against Defendant, ABBOTT LABORATORIES, and alleges as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff, ELNORA JONES (hereinafter "Plaintiff"), a resident of Shelby County, State of Tennessee, files the instant suit against Defendant, ABBOTT LABORATORIES (hereafter "Defendant" or "Abbott") seeking compensation for injuries and damages Plaintiff sustained as a result of Plaintiff's purchase and use of the prescription drug Humira (adalimumab).

2. Defendant Abbott is a corporation organized and existing under the laws of Illinois, having its principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064, and can be served via its agent for service of process, Laura J. Schumacher, at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott conducts business throughout the United States, including in the State of Tennessee. At all times

material hereto, Abbott manufactured, designed, tested, researched, developed, labeled, packaged, distributed, promoted, marketed, advertised, sold and/or otherwise placed Humira into the stream of commerce, including the State of Tennessee.

3. This Honorable Court has subject matter jurisdiction, pursuant to 28 U.S.C. §1332, as the amount in controversy exceeds $75,000 exclusive of interest and costs and because this action is brought by an individual who is a citizen of a state other than the Defendant.

4. Venue is proper in this district pursuant to 28 U.S.C. § 1391. Plaintiff purchased and used the product that forms the basis of this lawsuit in the State of Tennessee; Abbott's agents and representatives can be found in this district; Abbott conducts substantial business in the State of Tennessee and within this Federal District, including advertised, soliciting business and engaging in other persistent courses of conduct in this District, including receiving substantial compensation and profits from sales and use of Humira in this District.

FACTUAL ALLEGATIONS

5. Humira (otherwise known as adalimumab) is a recombinant human IcG1 antibody that neutralizes and/or blocks the activity of a pro-inflammatory cytokine known as tumor necrosis factor ("TNF").

6. A cytokine is a non-antibody protein that can be made by a wide range of cell types.

7. TNF is critical to the workings of the body's immune system. It is believed to play a role in the inflammation action of Crohn's Disease and also believed to act as a natural killer of cancer causing tumor cells in the body.

8. Crohn's Disease is an Inflammatory Bowel Disease generally involving inflammation in the lower part of the small intestine (called the ileum), although the disease can affect any part of the digestive tract, from the mouth to the arms.

9. Crohn's Disease can cause pain and frequent emptying of the bowels, often in the form of diarrhea.

10. Humira received approval from the U.S. Food and Drug Administration on Dec. 31, 2002 for the treatment of moderately to severely active rheumatoid arthritis.

11. In the treatment of rheumatoid arthritis, Humira is believed to bind specifically to TNF and block its interaction with certain cell surface TNF receptors, thereby interfering with endogenous TNF activity.

12. On or about September 2004, Plaintiff was infused with Humira as a treatment for her rheumatoid arthritis. She was infused with Humira on a regular basis thereafter through December 2005.

13. On or about June 2006, Plaintiff was diagnosed with lymphoma for which she subsequently underwent chemotherapy treatment. The direct and actual cause of Plaintiff's lymphoma was her use of Humira.

14. At all times relevant herein, Plaintiff was unaware of the serious side effects and dangerous properties of the drug as set forth herein.

15. Humira is the trade name for the prescription drug adalimumab, which at all times material hereto was manufactured, designed, tested, researched, developed, labeled, packaged, distributed, promoted, marketed, advertised, and/or sold (collectively referred to hereafter as "manufactured and sold") by the Defendant.

16. Abbott failed to warn consumers, including Plaintiff, of potential adverse side effects caused by Humira, including, but not limited to, lymphoma. To this date, Defendant has intentionally and continually downplayed the risk of adverse effects associated with Humira, such as lymphoma.

17. Humira was launched in the United States at the beginning of 2003, making sales of approximately $246 million in its first year alone. Within the third year of its introduction into the market, sales had reached $1.4 billion. During the first half of 2006, yearly sales are approximately $883 million, which is an increase of approximately 46% over that same period in 2005. Further growth of this drug is predicted, with peak sales in 2006 expected to reach about $1.9 billion.

18. Defendant materially breached its obligations to consumers, including Plaintiff, with respect its manufacturing and selling of Humira.

19. Defendant expressly and/or impliedly warranted to the consumer market, including to the Plaintiff, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials to the health care community, that Humira was safe, effective, fit and proper for its intended use.

20. Defendant is estopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from Plaintiff.

21. Defendant was aware of the substantial risks associated with the use of Humira but failed to fully disclose the same the health care community or consumers, including the Plaintiff.

COUNT I
STRICT LIABILITY – DESIGN DEFECT

22. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as though set forth in full in this cause of action.

23. At all time material hereto, Defendant has engaged in the business of manufacturing and selling Humira, and manufactured and sold this product in a defective condition unreasonably dangerous to consumers, including Plaintiff, in the State of Tennessee.

24. Humira was manufactured and sold by the Defendant, and was expected to reach, and did reach, consumers, including Plaintiff, without substantial change in the condition in which it left the possession of Defendant.

25. Plaintiff was a foreseeable consumer of Humira, and she used the medication for its intended purpose without any change in its condition.

26. Humira was defective and unreasonably dangerous for reasons which include, but are not limited to the following:

a. When placed in the stream of commerce, Humira contained unreasonably dangerous design defects and was not reasonably safe when used as intended, subjecting Plaintiff to risks that exceeded the benefits of the product;

b. When placed in the stream of commerce, Humira was defective in design and formulation, making its use more dangerous than an ordinary consumer would expect;

c. Humira was insufficiently and inadequately tested; and

d. Humira was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

27. At the time of the manufacture and sale of Humira, Defendant had knowledge of, and had available to them, a better, safer and/or different design for Humira that would have made the product safe and effective for consumers, including Plaintiff, but Defendant failed to use such a better, safer and/or different design.

28. Defendant, as manufacturer and seller of Humira, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the drug. Defendant had knowledge that their product was not safe as manufactured and sold by Defendant. Although Defendant knew or should have known that Humira could cause lymphoma, Defendant intentionally concealed this information from Plaintiff and from the general public.

29. The risk of dangerous side effects associated with Humira, including but not limited to the risk of lymphoma, was not known and could not have been discovered through the exercise of reasonable care by Plaintiff.

30. As a direct and proximate result of the defective and unreasonably dangerous condition of Humira, Plaintiff suffered what was diagnosed as lymphoma, and incurred economic and other damages as a result thereof.

31. Defendants conduct in manufacturing and selling Humira in such a defective and unreasonably dangerous condition was knowing and willful and performed with a

conscious disregard for the health and safety of the consuming public, including the Plaintiff.

32. Wherefore, Plaintiff is entitled to recover from Defendant, all damages caused by Defendant's defective and unreasonably dangerous product, including but not limited to, damages for pain, suffering, mental anguish and emotional distress, loss of the capacity to enjoy life, loss of past and future income, exemplary damages and court costs in an amount to be determined by the enlightened conscience of the jury and as demonstrated by the evidence.

COUNT II
STRICT LIABILITY – FAILURE TO WARN

33. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as though set forth in full in this cause of action.

34. Humira was manufactured and sold by the Defendant, and was expected to reach, and did reach, consumers, including Plaintiff, without substantial change in the condition in which it left the possession of Defendant.

35. Plaintiff was a foreseeable consumer of Humira, and she used the medication for its intended purpose without any change in its condition.

36. The Humira manufactured and sold by the Defendant and used by the Plaintiff was defective in that it contained insufficient warnings and instructions to alert reasonably prudent consumers, such as the Plaintiff, to the dangers posed by the product, including but not limited to, the danger and risk of lymphoma.

37. The Plaintiff could not, in the exercise of reasonable care, have discovered the nature and extent of the danger involved with using Humira and did not have knowledge of such dangers at or before the date she used the product. The nature and

extent of the danger involved in using Humira, including the danger of lymphoma, was simply not apparent to ordinary users of the product such as the Plaintiff.

38. As a direct and proximate result of the dangerously defective condition of Humira, Plaintiff suffered what was diagnosed as lymphoma, and Plaintiff incurred economic and other damages.

39. Defendant's conduct in failing to warn, as set forth above, was knowing, willful and performed with a conscious disregard for the health and safety of the consuming public, including the Plaintiff.

40. Wherefore, Plaintiff is entitled to recover from Defendant, all damages caused by Defendant's defective product including, but not limited to, damages for pain, suffering, mental anguish and emotional distress, loss of the capacity to enjoy life, loss of past and future income, exemplary damages and court costs in an amount to be determined by the enlightened conscience of the jury and as demonstrated by the evidence.

COUNT III
BREACH OF IMPLIED WARRANTY

41. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as though set forth in full in this cause of action.

42. Defendant is a "manufacturer" and "seller" who sold a "product" to Plaintiff as defined under Tennessee law. *See* Tenn. Stat. Ann. § 29-28-102.

43. The product or "goods," i.e., Humira, were not merchantable or fit for its particular purposes at the time it left the hands of the Defendant because Defendant impliedly warranted to medical professionals and Plaintiff that the product was effective

and safe for its intended use when in fact the product was not effective and safe for its intended use.

44. The Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendant.

45. The Plaintiff was prescribed, purchased and used the product for its intended purpose, and could not have known about the nature of the risks and side effects associated with the product until after she used it.

46. Conversely, Defendant had been provided notice of the injuries suffered by consumers like the Plaintiff prior to Plaintiff's use of the product by virtue of clinical trials and/or adverse events reported to the United States Food and Drug Administration and the National Cancer Institute in Maryland, among other organizations, prior to the product being placed on the market.

47. The physical injuries and damages complained of herein were caused proximately and in fact by the defective nature of the goods, said goods being of a defective and unreasonably dangerous condition at the time it left the hands of the Defendant.

48. Wherefore, Plaintiff is entitled to recover from Defendant, all damages caused by Defendant's defective product including, but not limited to, damages for pain, suffering, mental anguish and emotional distress, loss of the capacity to enjoy life, loss of past and future income, exemplary damages and court costs in an amount to be determined by the enlightened conscience of the jury and as demonstrated by the evidence.

COUNT IV
NEGLIGENCE

49. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as though set forth in full in this cause of action.

50. At all times material hereto, Defendant had a duty to consumers, including Plaintiff, to exercise reasonable and ordinary care in the manufacturing and selling of Humira.

51. Defendant breached the duty it owed the Plaintiff in ways which include, but are not limited to, the following:

a. Failure to exercise reasonable care in the manufacturing and selling of Humira;

b. Manufacturing and selling a product that it knew, or should have known, carried the risk of seriously debilitating and/or life threatening side effects;

c. Failure to adequately test Humira prior to placing the product on the market;

d. Failure to use care in the manufacturing and selling of Humira so as to avoid posing unnecessary health risks to users of such products;

e. Failure to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Humira;

f. Failure to advise consumers, including Plaintiff, that consumption of the medication could result in severe and disabling side effects, including but not limited to lymphoma;

g. Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to lymphoma;

h. Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Humira;

i. Disclosing that unreasonably dangerous characteristics of Humira existed at the time it left the control of the manufacturer or seller;

j. Failure to take immediate and direct measures to ensure that consumers and users of Humira, including Plaintiff, were notified, or that health care providers who prescribed this medication were notified, of such risks;

k. Failure to properly and adequately test Humira to determine the potential adverse health effects;

l. Any and all other acts of negligence with respect to Humira which may be shown at trial.

52. As a direct and proximate result of the Defendant's breach of the duty owed the Plaintiff, as set forth herein, Plaintiff suffered what was diagnosed as lymphoma, and Plaintiff incurred economic and other damages.

53. Defendant's breach was knowing, willful and performed with a conscious disregard for the health and safety of the consuming public, including the Plaintiff.

54. Wherefore, Plaintiff is entitled to recover from Defendant, all damages caused by Defendant's defective product including, but not limited to, damages for pain, suffering, mental anguish and emotional distress, loss of the capacity to enjoy life, loss of

past and future income, exemplary damages and court costs in an amount to be determined by the enlightened conscience of the jury and as demonstrated by the evidence.

COUNT V
VIOLATION OF THE TENNESSEE CONSUMER PROTECTION ACT
(Tenn. Code Ann. § 47-18-101 *et seq.*)

55. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as though set forth in full in this cause of action.

56. The conduct of the Defendant, as alleged herein, constitutes "trade," "commerce" and/or a "consumer transaction" and the offering of or providing of "goods" and/or "services" as defined in Tenn. Code Ann. § 47-18-103.

57. All of the acts and practices engaged in and employed by the Defendant, as alleged herein, are "unfair or deceptive acts or practices affecting the conduct of any trade or commerce" in Tennessee, which are declared unlawful by Tenn. Code Ann. § 47-18-104.

58. At all times material hereto, Defendant made misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Humira had defects, dangers, and characteristics that were other than what the Defendant had represented to the consuming public, including the Plaintiff, all in violation of § 47-18-101, *et seq*.

59. The Defendant's practice of promoting the product created and/or reinforced a false impression as to its safety.

60. The Defendant's practice of promoting the product placed and continues to place all consumers of Humira at risk for serious injury and potentially lethal side effects.

61. The Defendant's statements and omissions were made with the intent that the Plaintiff and her prescribing physician(s) would rely on such statements and omissions.

62. The Plaintiff purchased and used the subject product for personal reasons and suffered an ascertainable loss of money as a result of the Defendant's use or employment of the wrongful methods, acts and practices alleged herein.

63. The conduct of Defendant constitutes and was intended to constitute unlawful, unfair, deceptive and fraudulent business acts and practices within the meaning of Tenn. Code Ann. § 47-18-101, *et seq.*

64. The acts and business practices, as alleged herein, constituted and constitute a common, continuous, and continuing course of conduct of unfair, unlawful, deceptive and/or fraudulent business acts or practices within the meaning of Tenn. Code Ann. § 47-18-101, *et seq.*

65. Defendants' acts and business practices as described above are otherwise unfair, unconscionable, unlawful, deceptive and fraudulent.

66. As a direct and proximate result of the Defendant's acts of consumer fraud, the Plaintiff has suffered an ascertainable loss of money or other thing of value, including but not limited to the purchase price of the product and additional out-of-pocket health-care related costs, for which the Defendant is liable.

67. As a direct and proximate result of Defendant's acts of consumer fraud, the Plaintiff suffered severe and permanent injuries, including but not limited to, lymphoma.

68. Wherefore, Plaintiff requests relief and damages as allowed by Tenn. Code Ann. § 47-18-101, *et seq.*

PRAYER FOR RELIEF

69. Wherefore, Plaintiff demands judgment against the Defendant as follows:

a. Compensatory damages in an amount to be determined at trial;

b. Punitive damages in an amount to be determined at trial;

c. Pre-judgment and post-judgment interest;

d. Attorney's fees and treble damages pursuant to Tenn. Code Ann. § 47-18-101, *et seq.*;

e. Costs of the suit, including discretionary costs;

f. Such other and further relief as the Court deems just and proper under the circumstances.

DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff, ELNORA JONES, by and through counsel, and pursuant to Federal Rule of Civil Procedure 38, and hereby demands a trial by jury in this action.

Executed on this 15th day of February, 2007.

Respectfully submitted,

/s/ Neil D. Overholtz
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